February 24, 2026

David Lee
Staff Regulatory Affairs Specialist
Becton, Dickinson and Company
BD Integrated Diagnostic Solutions – Point of Care
7 Loveton Circle
Sparks, MD 21152
Re: Revocation of EUA201889

Dear David Lee:
This letter is in response to the request from Becton, Dickinson and Company ("BD"), in a letter dated January 29, 2026, that the U.S. Food and Drug Administration (FDA) withdraw the EUA for the BD Veritor System for Rapid Detection of SARS-CoV-2 issued on July 2, 2020, revised and reissued on January 13, 2021, and March 31, 2021, and amended on July 23, 2020, December 10, 2021, November 1, 2022, and March 21, 2023. FDA understands that as of the date of this letter there are no viable BD Veritor System for Rapid Detection of SARS-CoV-2 reagents remaining in distribution in the United States. As of the date of this letter, BD has fully transitioned to the BD Veritor System for SARS-CoV-2 product that was cleared under K243872.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because BD has requested that FDA withdraw the EUA for the BD Veritor System for Rapid Detection of SARS-CoV-2, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA201889 for the BD Veritor System for Rapid Detection of SARS-CoV-2, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the BD Veritor System for Rapid Detection of SARS-CoV-2 is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

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Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration